

REMARKS

Claims 1, 2, 26, and 37-58 constitute the pending claims in the present application, prior to Amendment.

Applicants add new claims 59-74. Support for the subject matter of the newly added claims is found throughout the specification. No new matter has been entered.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

1. Applicants note that the finality of the previous action has been withdrawn in view of the Request for Continued Examination received April 25, 2007.

2. Claims 1, 2, 26, 37-38, and 42-58 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Baron et al. (WO98/35020) in view of Porter et al. (US 6,613,798).

Applicants traverse this rejection.

Applicants contend that claims 1, 2, 26, 37-38, and 42-58 are patentable in view of the combined teachings of Baron et al. and Porter et al., either alone or when further combined with Pettet et al. and/or Ferrari et al. (of record). To establish a *prima facie* case of obviousness, the following three criteria must be met: (i) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (ii) there must be a reasonable expectation of success of combining the cited references to arrive at the claimed invention, and (iii) the prior art references must teach or suggest each and every limitation of the claimed invention. MPEP 2142-2143. As detailed in Applicants' previous reply, the cited references fail to teach or suggest a method of increasing expression of vascular endothelial growth factor (VEGF). The Examiner "acknowledges and concedes that none of the references teach inducing VEGF expression." *See*, page 5 of the instant Office Action. As such, the Examiner has acknowledged that the combined teachings of the cited references fail to establish a *prima facie* case of obviousness for, at least, failing to teach or suggest each and every limitation of the claimed invention.

The Examiner alleges that, despite the failure of the cited references to teach inducing VEGF expression, this limitation of the claimed invention "would flow naturally from following the suggestion of the prior art." Thus, this limitation allegedly cannot "be the basis for patentability when the differences would otherwise be obvious." *See*, page 5 of the instant

Office Action; citing *Ex parte Obiaya*. Applicants respectfully disagree with the factual and legal analysis relied on by the Examiner.

The Examiner has alleged that induction of VEGF expression would flow naturally from following the suggestion of the prior art. However, the Examiner has provided no evidence to support this statement. In contrast, Applicants provided references indicating that VEGF expression is not necessarily associated with angiogenesis. See, Belperio et al., 2000, J Leukocyte Biol 68: 1-8; Douglas and Nicolls, J Clinical Investigation, 2005, 115: 1133-1136, cited in Applicants' previous response. As such, the Examiner's allegation that VEGF expression, a feature completely absent from any of the cited references, would flow naturally from following the suggestion of the prior art is unsupported by any evidence of record.

However, regardless of the relationship between VEGF expression and treating cardiac ischemia, the alleged legal basis of the rejection is misplaced. The Examiner relies on *Ex parte Obiaya* as allegedly providing a legal basis for the rejection. However, the present case is distinguishable from *Obiaya* on, at least, three grounds. First, the claims at issue in *Obiaya* were directed to an apparatus. In contrast, the present claims are directed to methods.

Second, the inherent feature that allegedly distinguished the claimed device in *Obiaya* from the prior art was based on the use of the apparatus (in use the apparatus had the ability to obtain a shorter response time) not based on additional, patentable features incorporated into the apparatus itself. In other words, the claims in *Obiaya* did not affirmatively recite or require the presence of the very unrecognized feature that allegedly distinguished the claims from the prior art. In contrast, the present claims are specifically directed to a method of promoting expression of VEGF. VEGF expression is not merely an unrecognized property or unexpected advantage, but rather, promoting VEGF expression is an explicit feature recited in the claims.

Third, at issue in *Obiaya* was whether the patent applicant provided sufficient evidence of secondary considerations to rebut the *prima facie* case of obviousness. In contrast, at issue in the present case is whether the Examiner has satisfied the requirements for making a *prima facie* case of obviousness. For example, do the cited references teach or suggest each and every limitation of the claimed invention? As detailed above, the Examiner has acknowledged that the cited references fail to teach a method for promoting VEGF expression. As such, the cited references fail to teach each and every limitation of the claimed invention, and the Examiner has, by his own admission, failed to establish a *prima facie* case of obviousness.

Applicants' position is supported by applicable case law. Although inherency is often relevant in the context of anticipation, it is rarely relevant to an assessment of obviousness. See, for example, *Jones v. Hardy*, 727 F.2d 1524 (Fed. Cir. 1984); *In re Adams*, 53 C.C.P.A. 996 (CCPA 1966); *In re Caldwell*, 50 C.C.P.A. 1464 (CCPA 1963). Applicants fail to see how a feature of Applicants' claimed invention that was unrecognized, and thus neither taught nor suggested by the prior art, can form the basis of an obviousness rejection. "That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *Application of Spormann*, 53 C.C.P.A. 1375, 363 F.2d 444, 448, 150 U.S.P.Q. (BNA) 449, 452 (1966) (citing *In re Adams*, 356 F.2d 998, 53 CCPA).

Applicants contend that the Examiner has failed to establish a *prima facie* case of obviousness. The cited references fail to teach or suggest each and every limitation of the claimed invention, and the Examiner has specifically acknowledged this deficiency. The Examiner's reliance on the alleged inherent features of the prior art to bridge the gap between the teachings of the prior art and the claimed invention is misplaced. The concept of inherent obviousness is supported neither by *Ex parte Obiaya* nor by any applicable case law known to Applicants. Reconsideration and withdrawal of this rejection are respectfully requested.

3. Claims 39-41 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Baron et al. in view of Porter et al. and further in view of Igo et al. Applicants traverse this rejection.

As detailed above, the Examiner has failed to establish a *prima facie* case of obviousness with respect to claim 1. For example, the combined teachings of the cited references fail to teach or suggest a method of promoting VEGF expression. Igo et al. fail to overcome the deficiencies of the cited references. Accordingly, the combined teachings of Baron et al., Porter et al., and Igo et al fail to undermine the patentability of claims 39-41. If an independent claim, for example independent claim 1, is nonobvious under 35 U.S.C. 103, then any claim depending therefrom (e.g., claims 39-41) is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Reconsideration and withdrawal of this rejection are requested.

4. Applicants have added new claims 58-73. Applicants note that claims 58-73 are directed to subject matter similar to claims that were previously rejected as obvious in view of, for example, the combined teachings of Baron et al. and Porter et al. However, Applicants contend

that when making this rejection, the Examiner improperly relied on inherency to bridge the gap between the claimed invention and the teachings of the prior art. As detailed above, such reliance is misplaced and is inconsistent with case law regarding inherency doctrine. As such, Applicants submit that new claims 58-73 are nonobvious over the prior art and are in condition for allowance.

5. Applicants take this opportunity to direct the Examiner's attention to co-pending, commonly assigned application number 11/182,691 (publication number 2007-0110698). Prosecution in the co-pending application is currently ongoing. The most recent action was a Final Office Action mailed November 8, 2007. Applicants enclose herewith a Supplemental Information Disclosure Statement to make the co-pending application, as well as two related applications, of record.

CONCLUSION

In view of at least the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945 under Order No. CIBT-P01-119.**

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Respectfully Submitted,



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